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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/974,942	10/11/2001	Young W. Cho	A34471	1103

21003 7590 11/05/2003

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EXAMINER	
MOHAMED, ABDEL A	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/974,942	CHO ET AL.	
	Examin r	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5,6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

ACKNOWLEDGMENT OF THE IDS AND FORM PTO-1449, STATUS OF THE CLAIMS AND APPLICATION

1. The Information Disclosure Statements (IDS) and Form PTO-1449 filed 1/25/02, 2/28/02 and 12/13/02, respectively are acknowledged, entered and considered. Claims 1-18 are present for examination.

DISCLOSURE OBJECTED TO, MINOR INFORMALITIES

2. The disclosure is objected because of the following informalities: On page 5, line 8, in the recitation "via the-phosphate system". It appears that a word or a letter is missing due to typographical error. Appropriate correction is required.

OBJECTIONS TO TRADEMARKS AND THEIR USE

3. The use of trademark "SPHEREX®" has been noted in this application. Although, the use of trademark is permissible in patent applications, the proprietary nature of the mark should be respected and every effort made to prevent its use in a manner, which might adversely affect their validity as trademark.

Further, the specification, which specifies the generic terminology should include, published product information sufficient to show that the generic terminology or the generic description is inherent in the article referred by the trademark. This description requirement is made because the nature and composition of articles denoted by trademark can change and affect the adequacy of the disclosure.

CLAIMS REJECTION-35 U.S.C. § 102(b)

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9, 10, 12-15 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Cho (U.S. Patent No. 5,858,398).

The patent of Cho discloses a pharmaceutical composition comprising a core containing a pharmaceutically active agent such as insulin and the core is encapsulated with esterified fatty acid having a chain length of C_{14} or less or optionally containing a fatty acid having a chain length of C_{16} or greater in a concentration of about 5 w/v % or less. The pharmaceutical composition is prepared by admixing the pharmaceutically active agent (i.e., insulin), phospholipids, surfactants, and sterol, micronizing the admixture to from microparticles, and suspending the microparticles in at least one fatty acid of chain of length of C_{14} or less to form microparticles in micelles, wherein said pharmaceutical composition is administered orally to diabetic patients (See e.g., abstract, col. 3, lines 8-12, cols. 9 and 10, summary of the invention and claim 2) as directed to claims 1-6, 13, 17 and 18. With respect to the limitation wherein the C_{12}-C_{18} fatty acids are extracted from coconut of claim 7, such limitation is clearly disclosed on col. 20, lines 10 to 11, which states the final product was

spray coated with COCONADE (a commercial product of coconut oil of Kao Soap Co., Tokyo). Further, on Examples 1, 1A and claim 13, the reference shows encapsulation of the membrane with a film coating wherein the film coating comprises gelatin, wherein the gelatin is hardened having a mean diameter of about 0.5 to 1.5 mm. and formulated as a dry powder from. Thus, the dried product may be packed into a hard gelatin capsule or made into a pressed tablet, and as such meet the limitations of claims 9, 10, 12 and 14-15. Therefore, the prior art as shown above discloses methods of making and using a pharmaceutical composition comprising microparticles in micelle wherein the microparticles contains a pharmaceutically active agent such as insulin encapsulated with a membrane of esterified C_{12}-C_{18} fatty acids and administered orally to diabetic patients, and as such anticipates claims 1-7, 9, 10, 12-15 and 17-18 as drafted.

5. Claims 1-6 and 8-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Cho et al., (U.S. Patent No. 5,656,289).

The patent of Cho et al., discloses a pharmaceutical composition comprising a core containing a pharmaceutically active agent such as insulin and the core is encapsulated with for example, C_{16} to C_{24} saturated or unsaturated fatty acid, optionally esterified and having a concentration of from 0 to 10% w/v, for example 0.1 to 5% w/v of the formulation as a whole. The pharmaceutical composition is prepared by admixing the pharmaceutically active agent (i.e.,

insulin), phospholipids, surfactants, and sterol, micronizing the admixture to from microparticles, and suspending the microparticles in at least one fatty acid of chain of length of C_{16} to C_{24} or less to form microparticles in micelles, wherein said pharmaceutical composition is administered orally to diabetic patients (See e.g., abstract, cols. 3-10, 15, Examples 1-4) as directed to claims 1-6, 13, 17 and 18. With respect to the limitations wherein the membrane is about 0.02 mm thick (claim 8); and wherein a minicapsule having a diameter of about 1.8 to 3.0 mm., such limitations are already disclosed on col. 14, lines 20-26, which states the thickness of enteric coating on tablets or capsules can be, for example, from 0.5 to 4 microns in thickness, although the precise thickness will be determined by the skilled formulator, as such overlaps with 0.02 mm thickness of claim 8 because 0.02 mm is 2 micron. Also, the reference shows that the minicapsule or microcapsule has a diameter of 0.5 to 2 mm, which overlaps, with a diameter of about 1.8 to 3.0 mm of claims 11 and 16. Further, on cols. 12, 14 and Examples 5-16, the reference shows encapsulation of the membrane with a film coating wherein the film coating comprises gelatin, wherein the gelatin is hardened and formulated as a dry powder from. Thus, the dried product may be packed into a hard gelatin capsule or made into a pressed tablet, and as such meet the limitations of claims 9, 10 and 12-15. Therefore, the prior art as shown above discloses methods of making and using a pharmaceutical composition comprising microparticles in micelle wherein the microparticles contains a pharmaceutically active agent such as insulin encapsulated with a membrane of

esterified C_{12}-C_{18} fatty acids and administered orally to diabetic patients, and as such anticipates claims 1-6 and 8-18 as drafted.

6. Claims 1-5, 9, 10, 12-15 and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakagame et al., (U.S. Patent No. 4,615,885).

The patent of Nakagame et al., discloses a pharmaceutical composition comprising a core containing a pharmaceutically active agent such as urokinase and the core is encapsulated with esterified fatty acid having a chain length of C_{10}-C_{20}, preferably the concentration of fatty acids in the composition is 15% by weight or lower. The pharmaceutical composition is prepared by admixing the pharmaceutically active agent (i.e., urokinase), phospholipids, surfactants, and sterol, micronizing the admixture to from microparticles, and suspending the microparticles in at least one fatty acid of chain of length of C_{18}-C_{20} or less to form microparticles in micelles, wherein said pharmaceutical composition is administered orally to patients (See e.g., abstract, cols. 2-4, and claim 2) as directed to claims 1-5, 13, 17 and 18. Further, on col. 3, lines 19-26 and Examples 1-4, the reference shows encapsulation of the membrane with a film coating wherein the film coating comprises gelatin, wherein the gelatin is hardened and formulated as a dry powder from. Thus, the dried product may be packed into a hard gelatin capsule or made into a pressed tablet, and as such meet the limitations of claims 9, 10, 12 and 14-15. Therefore, the prior art as shown above discloses methods of making and using a pharmaceutical

composition comprising microparticles in micelle wherein the microparticles contains a pharmaceutically active agent such as insulin encapsulated with a membrane of esterified C_{10}-C_{20} fatty acids and administered orally to diabetic patients, and as such anticipates claims 1-5, 9, 10, 12-15 and 17-18 as drafted.

CLAIM REJECTIONS-35 U.S.C. § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al. (U.S. Patent No. 5,656,289) taken with Cho (U.S. Patent No. 5,858,398).

The reference Cho et al., as discussed in 102(b) rejection above, discloses a pharmaceutical composition comprising a core containing a pharmaceutically active agent such as insulin and the core is encapsulated with (for example, C_{16} to C_{24} saturated or unsaturated fatty acid, optionally esterified and having a concentration of from 0 to 10% w/v, for example 0.1 to 5% w/v of the formulation as a whole. The pharmaceutical composition is prepared by admixing the pharmaceutically active agent (i.e., insulin), phospholipids, surfactants, and sterol, micronizing the admixture to from microparticles, and suspending the microparticles in at least one fatty acid of chain of length of C_{16} to C_{24} or less to form microparticles in micelles, wherein said pharmaceutical composition is administered orally to diabetic patients (See e.g., abstract, cols. 3-10, 15, Examples 1-4). With respect to the limitations wherein the membrane is about 0.02 mm thick (claim 8); and wherein a minicapsule having a diameter of about 1.8 to 3.0 mm., such limitations are already disclosed on col. 14, lines 20-26, which states the thickness of enteric coating on tablets or capsules can be, for example, from 0.5 to 4 microns in thickness, although the precise thickness will be determined by the skilled formulator, as such overlaps with 0.02 mm thickness of claim 8 because 0.02 mm is 2 micron. Also, the reference shows that the minicapsule or microcapsule has a diameter of 0.5 to 2 mm, which overlaps, with a diameter of about 1.8 to 3.0 mm of claims 11 and 16. Further,

on cols. 12, 14 and Examples 5-16, the reference shows encapsulation of the membrane with a film coating wherein the film coating comprises gelatin, wherein the gelatin is hardened and formulated as a dry powder from. Thus, the dried product may be packed into a hard gelatin capsule or made into a pressed tablet. Therefore, the prior art as shown above discloses methods of making and using a pharmaceutical composition comprising microparticles in micelle wherein the microparticles contains a pharmaceutically active agent such as insulin encapsulated with a membrane of esterified C_{12}-C_{18} fatty acids and administered orally to diabetic patients.

The reference differs from claims 1-18 in not teaching a composition having C_{12}-C_{18} fatty acids extracted from coconut. Although, the primary reference discloses a pharmaceutical composition comprising microparticles in micelle wherein the microparticles contains a pharmaceutically active agent such as insulin encapsulated with a membrane of esterified C_{12}-C_{18} fatty acids, however, the reference is silent with respect to the extraction of C_{12}-C_{18} fatty acids (i.e., the source of the fatty acids). Nevertheless, the secondary reference '398 patent on col. 20 shows that COCONADE extract of coconut oil in combination with gelatin is used in the process of microcapsulation for the intended purposes of preserving the chemical and pharmacological activities, as well as the stability of the final product. Thus, in view of this, the subject formulation may be used in combination with other condition to provide a wide variety of fatty acids or may be tailored for specific fatty acid (i.e. extracted from

coconuts). Therefore, the claimed specific fatty acid which is extracted from coconut, which fall within the scope of the prior art would have been prima facie obvious from said prior art disclosure to a person of ordinary skill in the art at the time the invention was made. Applicants claims are directed to optimization of an "art recognized variable" which is well within the purview of one of ordinary skill in the art, In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Thus, the combined teachings of the prior art makes *prima facie* obvious the claimed invention's of employing fatty acids which are extracted from coconut oil in combination with gelatin to be used in the process of microcapsulation for the intended purposes of preserving the chemical and pharmacological activities, as well as the stability of the final product thereof, absent of sufficient objective factual evidence or unexpected results to the contrary.

CONCLUSION AND FUTURE CORRESPONDENCE

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The appropriate fax phone number for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196

Mohamed/AAM

November 3, 2003

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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